



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: N-butyldeoxynojirimycin to treat Smith-Lemli Opitz Syndrome (SLOS) and diseases that exhibit a similar NPC-like cellular phenotype.

AGENCY: National Institutes of Health, DHHS.

ACTION: Notice

SUMMARY: The National Institute of Child Health and Human Development, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the U.S. and foreign Patents and Patent Applications listed in the Supplementary Information section of this notice to SubRed Pty Ltd located in Australia, registered in Victoria.

DATES: Only written comments and/or applications for a license which are received by the National Institute of Child Health and Human Development c/o National Cancer Institute's Technology Transfer Center on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Alan Hubbs,

Ph.D., Senior Technology Transfer Manager at Telephone (240)-276-5530 or at Email: hubbsa@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The following represents the intellectual property to be licensed under the prospective agreement:

Intellectually Property

1. Great Britain Patent Application No. 712494.4, filed on June 27, 2007 [HHS Reference No. E-206-2007-0-GB-01];
2. PCT Patent Application No. PCT/GB2008/002207, filed June 26, 2008 [HHS Reference No. E-206-2007-0-PCT-02];
3. Issued Australian Patent No. 2008269585, filed on June 26, 2008, Issued July 2, 2015 [HHS Reference No. E-206-2007-0-AU-03];
4. Issued Canadian Patent No. 2691937, filed on June 26, 2008, Issued January 23, 2018 [HHS Reference No. E-206-2007-0-CA-04];
5. Issued European Patent No. 2182936, filed on June 26, 2008, Issued April 1, 2020 [HHS Reference No. E-206-2007-0-EP-05];
6. Issued US Patent No. 8,557,844, filed January 19, 2010, Issued October 15, 2013 [HHS Reference No. E-206-2007/0-US-06];
7. Issued United States Patent No. 9,428,541, filed on September 13, 2013, Issued August 30, 2016 [HHS Reference No. E-206-2007-0-US-09]

With respect to persons who have an obligation to assign their right, title and interest to the Government of the United States of America, the patent rights in these inventions have been assigned to the Government of the United States of America. The prospective exclusive license territory may be world-wide, and the field of use may be limited to the use of Licensed Patent Rights for the following: “The use of N-

butyldeoxynojirimycin in humans to treat Smith-Lemli Opitz Syndrome (SLOS) and diseases that exhibit a similar NPC-like cellular phenotype..”

This technology discloses pharmaceutical compositions and methods of use to treat SLOS and diseases having a secondary NPC like cellular phenotype or wherein the disease is an inborn error in cholesterol synthesis.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Institute of Child Health and Human Development receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: March 22, 2021.

Richard U Rodriguez
Associate Director
Technology Transfer Center
National Cancer Institute